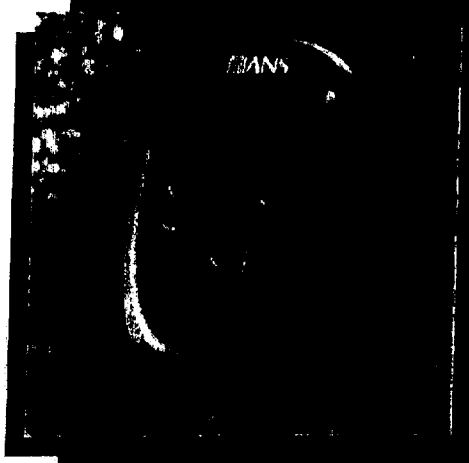
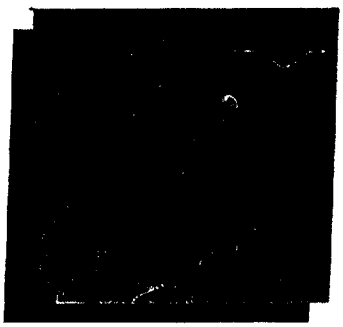
Genesis™

Neurostimulation System





Programmer User's Guide

ANS
LIFE GETS BETTER

USER'S GUIDE

Neurostimulation has been shown to benefit patients with certain types of chronic intractable pain conditions. It uses a method of pain control that replaces areas of chronic pain with a more pleasant tingling or massaging sensation called paresthesia.

This manual will help you understand how to use and care for your Genesis Implantable Pulse Generator (IPG) and Programmer. Thoroughly review this manual before using your system and ask anyone involved in your care to also read it.

If you have questions beyond those addressed in this manual, or if an unusual situation arises, consult your physician. Your physician is familiar with your medical history and can give you more detailed information.

For assistance or questions about the system not covered in this manual call:

1 (800) 727-7846 or (972) 309-8000

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

CONTENTS

PATIENT MANUAL

INDICATIONS FOR USE, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS

Indications For Use

The Genesis (IPG) Neurostimulation System is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs including unilateral or bilateral pain associated with any of the following: failed back surgery syndrome, and intractable low back and leg pain.

Contraindications

The system is contraindicated for patients with demand type cardiac pacemakers.

If you are unable to operate the system or fail to receive effective pain relief during trial stimulation you cannot be implanted with a SCS.

Warnings

This section lists the potential hazards associated with spinal cord stimulation that you must be aware of to avoid serious outcomes that may cause injury or death.

You should not use Spinal Cord Stimulation (SCS) if you are a poor surgical risk, have multiple illnesses or active general infections.

Diathermy Therapy – You cannot have any short-wave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) on your body if you have any part of a spinal cord stimulator implanted. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy is further prohibited because it may also damage the neurostimulation system components resulting in loss of therapy, requiring additional surgery for system implantation and replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned "On" or "Off." You are advised to inform their health care professional that you cannot be exposed to diathermy treatment.

Operation of Machines, Equipment, and Vehicles — Do not drive, operate heavy machinery or power tools with the stimulator turned on. Postural changes or abrupt movements could cause over-stimulation (jolting sensation) that might cause you to lose control of your vehicle or equipment.

Magnetic Resonance Imaging (MRI) — You should NOT be subjected to an MRI. The electromagnetic field generated by an MRI may dislodge implanted components, damage the device electronics, and induce voltage through the lead that could cause a jolting or shocking sensation.

Theft Detectors and Metal Screening Devices — Certain types of antitheft devices such as those used at entrances/exits of department stores, libraries, and other public establishments, and/or airport security screening devices may affect stimulation. It is possible that patients who are

Theft Detectors and Metal Screening Devices — Certain types of antitheft devices such as those used at entrances/exits of department stores, libraries, and other public establishments, and/or airport security screening devices may affect stimulation. It is possible that patients who are implanted with non-adjacent multiple leads and/or patients that are sensitive to low stimulation thresholds may experience a momentary increase in their perceived stimulation, which has been described by some patients as uncomfortable or jolting. It is recommended that patients use caution when approaching such a device and request assistance to bypass the device. If they must proceed through the device the patient should turn off the stimulator and proceed with caution, ensuring to move through the detector quickly.

Lead Movement — Avoid bending, twisting, stretching, or lifting objects over five pounds, for six to eight weeks post-implantation. Extension of the upper torso or neck may cause lead movement and alter the stimulation field (especially with leads in the cervical area), resulting in overstimulation or ineffective stimulation.

Explosive or Flammable Gases — Do not use the programmer in an environment where explosive or flammable gasses are present.

Cardiac Pacemakers — Implanted neurostimulation systems may adversely affect the operation of implanted cardiac demand pacemakers.

Pediatric Use — Safety and effectiveness of spinal cord stimulation has not been established for pediatric use.

Pregnancy — Safety for use during pregnancy has not been established.

Cardioverter Defibrillators — Neurostimulation systems may adversely affect the programming of implanted cardioverter defibrillators.

Postural Changes — Changes in posture or abrupt movements can change the level of stimulation and potentially cause unpleasant sensations. Turn your IPG off or lower the amplitude before stretching, lifting your arms over your head, or exercising. If unpleasant sensations occur, the IPG should be turned off.

PRECAUTIONS

This section lists the actions you should be aware of and avoid to prevent situations that may cause uncomfortable sensations or damage to your neurostimulation system.

Keep the Programmer Dry — Do not use the programmer when engaging in activities that might cause the programmer to get wet, such as exposure to rain, swimming, bathing, etc. Your programmer is not waterproof and should be kept dry to avoid damage.

Handle the Programmer With Care — The programmer is a sensitive electronic device that can be damaged by rough handling, including dropping on the ground or being crushed.

Battery Care — Batteries can explode, leak or melt if disassembled, shorted (when battery connections contact metal), or exposed to high temperature or fire.

Disconnecting the Wand — Do not pull directly on the cord to disconnect the wand from the programmer. Doing so can damage the cord and make the wand inoperable. To disconnect the wand, grasp the connector at the contoured finger grips and pull gently downward.

Medical Tests and Procedures — Before undergoing medical tests or procedures, contact your physician to determine if the procedure will cause you injury or damage your neurostimulation system. Specifically, you should be aware that medical devices such as electrohydraulic lithotriptors, therapeutic x-rays, cobalt machines, and linear accelerators may cause damage to the electronic circuitry of an implanted neurostimulation system.

Electromagnetic Interference (EMI) — Certain commercial electrical equipment (arc welders, induction furnaces, resistance welders), communication equipment (microwave programmers, linear power amplifiers, high-power amateur transmitters), and high-voltage power lines may generate sufficient EMI to interfere with neurostimulation operation if approached too closely. Use caution when approaching such devices and turn your IPG off if you feel any unusual sensations. Do not turn the IPG on again until you are away from the area of EMI interference.

Control of Your Programmer — Keep your programmer out of the hands of children in order to avoid the potential of damage or unauthorized change in stimulation parameters.

Physician Instructions — Always follow the programs and therapy instructions established for you by your physician. Failure to do so may cause the therapy to be less effective in providing pain relief.

Unauthorized Programming Changes — Do not make unauthorized changes to physician established stimulation parameters. If you find yourself in an unfamiliar screen display, press the previous screen key.

Magnet Usage — The magnet provided with your Genesis system is a high powered magnet intended for use solely with the Genesis system. Keep it away from watches, credit cards, computer disks and other magnetic sensitive items to avoid damaging them. Always place the "Keeper Bar" on the magnet when not in use.

FCC Statement — FCC ID: PX 2001 — This device (Patient Programmer) complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Case Damage — If the IPG case is pierced or ruptured, severe burns could result from exposure to the battery chemicals.

Cellular Phones — The effect of cellular phones on spinal cord stimulators is unknown and patients should avoid placing cellular phones directly over the device.

High Output Ultrasonics and Lithotripsy — The use of high output devices such as an electrohydraulic lithotriptor may cause damage to the electronic circuitry of an implanted IPG. If lithotripsy must be used, do not focus the energy near the IPG.

Ultrasonic Scanning Equipment — The use of ultrasonic scanning equipment may cause mechanical damage to an implanted neurostimulation system if used directly over the implanted device.

External Defibrillators — The safety of discharge of an external defibrillator on patients with implanted neurostimulation systems has not been established.

Therapeutic Radiation — Therapeutic radiation may damage the electronic circuitry of an implanted neurostimulation system, although no testing has been done and no definite information on radiation effects is available. Sources of therapeutic radiation include therapeutic x-rays, cobalt machines, and linear accelerators. If radiation therapy is required the area over the implanted IPG should be shielded with lead.

Adverse Effects

The implantation of a neurostimulation system involves risk. In addition to those risks commonly associated with surgery, the following risks are also associated with implantation, and/or use of a neurostimulation system:

- Undesirable changes in stimulation may occur over time. These changes in stimulation are possibly related to cellular changes in tissue around the electrodes, changes in the electrode position, loose electrical connections and/or lead failure.
- Placement of a lead in the epidural space is a surgical procedure that may expose the patient to risks of epidural hemorrhage, hematoma, infection, spinal cord compression, and/or paralysis.
- Stimulation at high outputs may cause unpleasant sensations or motor disturbances (including movement). If unpleasant sensations occur, turn the IPG off immediately.
- Battery failure and/or battery leakage may occur.
- Radicular chest wall stimulation.
- CSF leakage.
- Persistent pain at the electrode or IPG site.
- Seroma at the implant site.
- Lead migration, which can result in changes in stimulation and subsequent reduction in pain relief.
- Allergic or rejection response to implant materials.
- Implant migration and/or local skin erosion.
- Paralysis, weakness, clumsiness, numbness or pain below the level of implantation.

PATIENT MANUAL

GENESIS (IPG) NEUROSTIMULATION SYSTEM CLINICAL SUMMARY

The safety and effectiveness of the Genesis (IPG) Neurostimulation System was determined based on available published clinical studies for similar totally implanted spinal cord stimulation systems. The ANS IPG device is similar to the SCS systems reported in published literature in intended use, target patient population, technology, device design, and output characteristics. Therefore, the clinical data from the published literature described below represents evidence supporting the safety and effectiveness of the Genesis (IPG) Neurostimulation System for use as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back and leg pain.

EFFICACY EVALUATION

Three (3) clinical literature studies were used to assess the safety and effectiveness of the Genesis (IPG) Neurostimulation System (Ohnmeiss et al. 1996, Villavicencio et al. 2000, Hassenbusch SJ et al. 1995). The studies included a total of 116 patients that were implanted with an SCS system. A total of approximately 3166 device months of experience was considered in the retrospective clinical evaluation. All three studies examined the effectiveness of SCS on patients with chronic pain of the trunk and/or limbs including unilateral or bilateral pain associated with the following: failed back surgery syndrome or intractable low back and leg pain. In all studies, an identified totally implantable spinal cord stimulator was used in association with a quadripolar percutaneous epidural lead or a quadripolar lead. These studies provide the same diagnostic or therapeutic intervention for the same disease/conditions and patient population as the Genesis (IPG) Neuromodulation System.

The prospective study by Ohnmeiss et al. 1996 examined the long-term effectiveness of SCS in patients with intractable leg pain. 40 patients were implanted with SCS systems and evaluated at 6 weeks, 12 months, and 24 months follow-up. Outcome measures included the VAS, pain drawings, medication use, SIP, isometric lower extremity testing, and patient questionnaires. An intent to treat analysis was performed. After patients had SCS for 24 months, leg pain, pain when walking, standing pain, pain's effect on overall lifestyle, and the total analog scale scores were significantly improved from baseline. In this study, SCS was effective in improving intractable leg pain.

In addition, 3 patients from this study had their stimulators repositioned due to pain at the original location. 3 patients had reoperations to adjust lead position; 1 patient required 2 reoperations, 1to have the device removed due to infection and later to have a new device implanted. A diabetic patient had skin problems which required device removal; a new device was later implanted. Two patients had the device removed due to unsatisfactory pain relief.

The prospective study by Villavicencio et al. 2000 included 41 patients with pain of various etiologies. The majority of the patients, 24 (59%), had Failed Back Surgery Syndrome (FBSS), 7 (17%) had Complex Regional Pain Syndrome) CRPS I and II, 4 (10%) had neuropathic pain syndrome, and 6 (15%) were diagnosed as stroke or other. Patients underwent an initial trial period

period for SCS with temporary leads. If the trial resulted in greater than 50% reduction in the patient's pain, as measured by the VAS, the patient was implanted with a SCS system. In the study, 27/41 (66%) patients had permanent implants. All patients were examined after 6 weeks. Pain measurements were assessed at 3-6 month intervals for the first year and annually thereafter. The median long-term follow-up was 34 months. A total of 24/27 (89%) patients reported greater than 50% reduction in pain.. Since the majority of the patients were treated for FBSS, this article supports the use of SCS for the treatment of FBSS.

In this study, 1 patient required a revision because of electrode fracture. One patient required removal of the system due to local infection. One patient required replacement of the IPG due to mechanical failure. Overall, 16 of 27 (59%) patients required a total of 36 repositioning procedures.

A retrospective analysis by Hassenbusch SJ et al. 1995 that included patients with chronic lower body pain, predominately neuropathic pain and pain either midline lower back and/or unilateral or bilateral leg pain treated over a 5 year period. The study was a comparison of SCS to spinal infusion of opioids. For patients with radicular pain involving one leg with or without unilateral buttock pain, a trial of SCS was recommended first. For patients with midline back pain and /or bilateral leg pain, a trial of long-term spinal infusion was recommended first. If the patients failed screening with either of these modalities, the other was then tested. If the treatment reduced the pain by 50%, the systems were internalized. A retrospective analysis of patients with unilateral leg and/or buttock pain treated initially with SCS and bilateral leg or mainly low back pain treated initially with spinal infusions of opioids was then done.

In this study, 42 patients were screened; 26 (62%) patients received spinal stimulation; 16 (38%) received opioids via a spinal infusion pump. A total of 5 patients did not receive adequate pain relief with SCS; 3 (7%) of these patients underwent trial spinal infusions and had effective pain relief. There were of 4 (10%) patients that underwent a trial of spinal infusion of opioid but did not receive adequate pain relief; these patients were not tested with SCS. Pain severity was rated using a verbal digital pain scale: "On a scale of 0 to 10 where 0 is no pain and 10 is the worst pain you could ever imagine, what is your pain now?" (Hassenbusch SJ et al. 1995) 16/26 patients (62%) had greater than 50% pain relief with SCS. A total of 2/16 (13%) patients had greater than 50% pain relief with opioids. Mean follow-up was 2.1 + 0.3 years. This analysis supports the use of SCS for intractable low back and leg pain.

In this study, 7 (17%) patients suffered complications after implantation of the device; 5 (12%) patients required repositioning of catheter type electrodes and 2 patients required revision of the stimulator generator.

Safety Evaluation

Sixteen (16) studies were identified based on the detailed inclusion/exclusion criteria to demonstrate the safety of the Genesis (IPG) Neurostimulation System (all references in the Bibliography were used). The studies included a total of 1,253 patients.

SUMMARY OF RISKS IDENTIFIED IN THE RETROSPECTIVE CLINICAL STUDIES

Risks	*# of Patients*	*# of Events*	*% of Patients*
Lead Migration	1059	144	13.6
Infection	1253	37	3.0
Epidural Hemorrhage	1253	0	0
Seroma	1253	0	0
Hematoma	1253	5	0.4
Paralysis	1253	1	0.1
CSF Leak	1253	6	0.5
Over/Under Stim	1059	27	2.6
Intermittent Stim	1059	0	0
Pain over Implant	1059	12	1.1
Allergic Reaction	1059	2	0.2
Skin Erosion	1059	1	0.1
Lead Breakage	1059	182	17.2
Hardware Malfunction	1059	32	3.0
Loose Connection	1059	10	1.0
Battery Failure	911	17	1.9
Other	1059	24	2.3

The above table depicts the number of patients, the number of events observed, and the percentage of occurrences of each event compared to the total number of patients. It should be noted that several studies include both IPG and RF Systems. The clinical experience reported in the literature on RF systems is relevant to determining the safety of totally implantable IPG systems.

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SYSTEM REGISTRATION

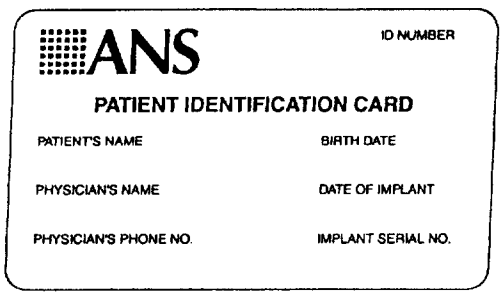
WHY SHOULD I REGISTER MY GENESIS NEUROSTIMULATION SYSTEM?

You will be sent a personal medical identification card. This small card:

- Identifies you as having an implanted medical device.
- Helps you pass through security systems like those in airports.
- Provides emergency information that allows your physician to be contacted.
- Activates the system warranty.

If you have questions about your card or system registration call ANS Customer Service at:

(800) 727-7846 or (972) 309-8000.



SERVICE INFORMATION

If your system needs service or repair, call ANS Customer Service toll-free at 1 (800) 727-7846 or (972) 309-8000 for instructions.

PATIENT ACCESSORIES AND ORDERING INFORMATION

To place an order, please contact ANS Customer Service toll-free at 1 (800) 727-7846 or (972) 309-8000.

Order Number	Product Description
1210	System Magnet
1232	Wand
1253	Battery Pack for AAA Batteries
1272	System Storage Case

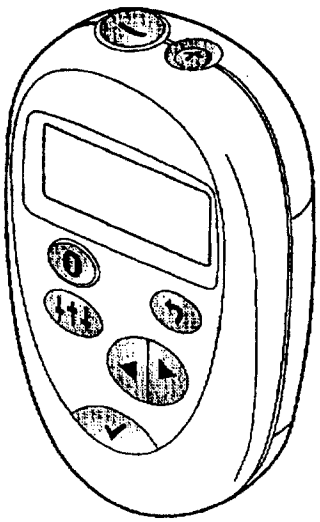
PATIENT MANUAL

SYSTEM DESCRIPTION

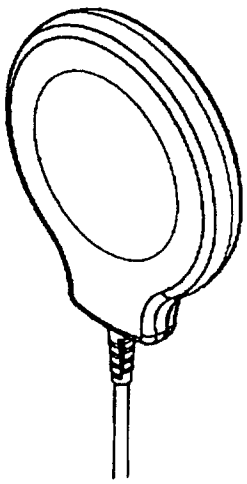
The Genesis Neurostimulation System is an implanted pulse generator that delivers low-level electrical impulses to selected nerve fibers as a method of pain control that works well for certain types of chronic intractable pain. The electrical impulses are believed to stop pain messages from being transmitted to the brain and replaces areas of pain with a tingling or massaging sensation called paresthesia or stimulation.

The Genesis Neurostimulation System is intended to be used with ANS leads (3143, 3146, 3153, 3156, 3183, 3186, 3222, 3240, 3244, 3280) and extensions (3341, 3342, 3343, 3346, 3382, 3383, 3386).

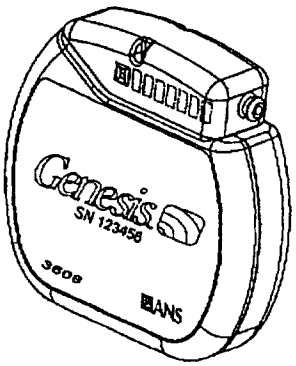
THE GENESIS NEUROSTIMULATION SYSTEM CONSISTS OF FOUR PRIMARY COMPONENTS:



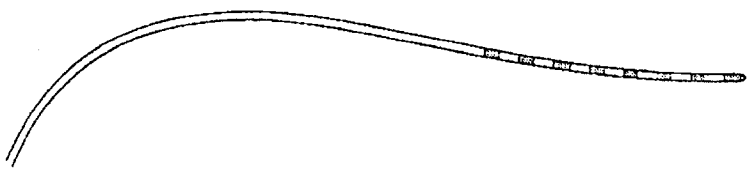
PATIENT PROGRAMMER
The Genesis Programmer enables full patient control through the selection of clinician prescribed programs for downloading to the IPG.



PROGRAMMING WAND
The wand provides two-way communication capability for uploading and downloading information between the IPG and the programmer.



IPG
The Genesis implanted pulse generator contains a battery and electronics for generating electrical impulses to the leads.



LEAD
The lead is a thin cable or small paddle that is implanted in the space above the spinal cord or near a selected nerve. Metal electrodes along the lead deliver low-level electrical impulses to the desired area.

DEFINITIONS

Amplitude — A measure of the strength of the stimulation signal generated by the IPG. Think of amplitude as the volume control on a radio. When you increase amplitude, the tingling sensation increases in strength. When you decrease amplitude, you feel less tingling.

MultiStim® Program — An optional stimulation program type comprised of two individual stim sets that provide stimulation to different body areas. The system activates each stim set automatically to provide overlapping stimulation coverage.

Paresthesia — The tingling or massaging sensation created by low-level electrical stimulation that can help mask the presence of certain types of chronic pain, also known as stimulation.

Program or Stimulation Program — A series of pre-defined stim sets programmed into the programmer that can be selected and used to meet changing pain requirements. The number of programs available is determined by your physician.

Programming — The selection and adjustment of stimulation parameters by your physician or clinical team. Once the best parameters for your pain control therapy are selected, they are stored in the programmer.

Stimulation Modes:

- **Continuous** — Provides constant stimulation until it is manually turned off or until 18 continuous hours of stimulation. The IPG will automatically turn off after 18 consecutive hours of stimulation to remind you to be conscious of battery usage and conserve the battery. Simply recommunicate with the IPG to resume stimulation and your IPG will provide stimulation for another 18 hours.
- **Cycle** — Automatically administers stimulation on and off times for controlled stimulation reducing battery usage time while maintaining optimal stimulation.
- **Bolus** — Allows for stimulation to be provided in set amounts of time. After stimulation elapses an automatic lock-out phase is entered. Upon completion of the lock-out period, the patient can bolus themselves again.

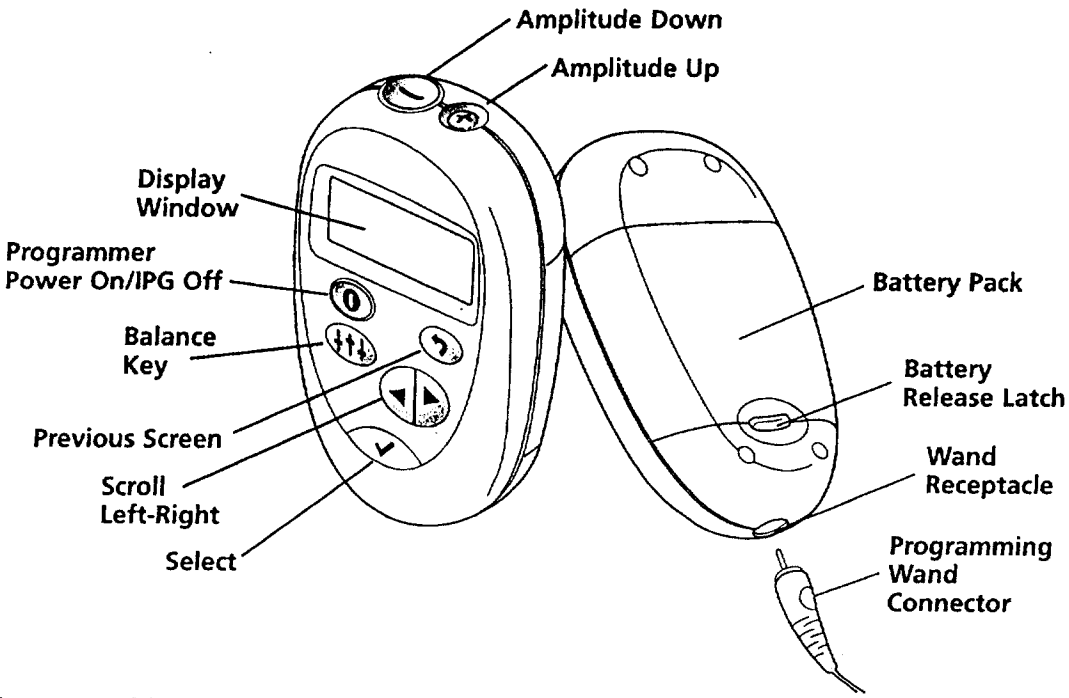
Stimulation Parameter — A setting that can be changed during programming by your physician or clinical team to optimize your stimulation therapy.

Stim or Stimulation — The massaging or tingling sensation known as paresthesia. It is created by low-level electrical stimulation that can help mask the presence of certain types of chronic pain.

Stim Set or Stimulation Set — A combination of stimulation parameters created by your physician or clinical team and programmed into your programmer to provide paresthesia to a specific anatomic location.

Single Program — A single set of stimulation parameters that can be designated to a specific stimulation mode for delivery of the selected therapy.

THE GENESIS PROGRAMMER



FUNCTION KEYS

Amplitude Down Key — Used to decrease the amplitude.

Amplitude Up Key — Used to increase the amplitude.

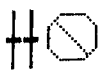
Programmer Power On/IPG Off Key — Used to turn the programmer power on and the IPG off. The programmer will automatically turn off after 1 minute of inactivity.

Previous Screen Key — Used to return the display to the previous screen or cancel the last screen action.

Scroll Keys — Used to move from one program to another on your display screen. You can also scroll from the Program to Menu Modes. Within the menu, you scroll across the choices displayed on the screen.

FUNCTION KEYS (CONTINUED)

Balance or Stim-Set Balance Key — Used to make individual amplitude adjustments to selected stim sets.

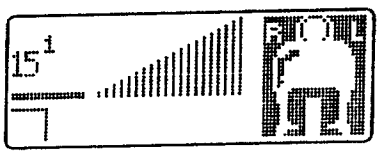


NOTE: If amplitude is not active, an "invalid" symbol will be displayed when the Balance key is pressed.

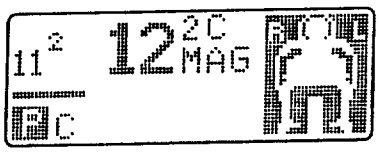
Select Key — Used to select and activate menu changes. Also used to start the program that is shown on the display window. Pressing the Select key activates that program.

DISPLAY SCREENS AND INDICATORS

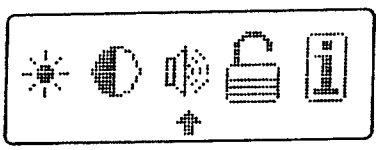
Operational Display Screen — The display window that is shown when the programmer is in the Stimulation (operation) mode (see page 13).



Program Selection Screen — The display window that is shown when the programmer is in the Program Selection mode (see page 19).



Menu — The display window that provides information and control of the display characteristics, sound qualities, and wand placement. It also provides information about your system (see page 25).



Stimulation (Stim) Diagram or Map — A map or diagram showing the areas of stimulation (paresthesia coverage) as a result of a selected program.

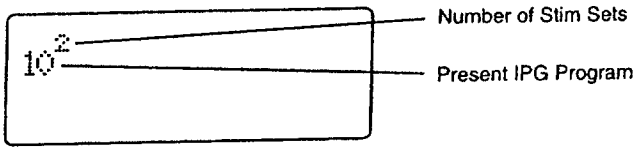
NOTE: This is an optional setting that may not be included as part of your therapy as determined by your physician. If this is the case, and a stimulation diagram is not included, the graphic to the right will be displayed.

THE OPERATIONAL DISPLAY SCREEN

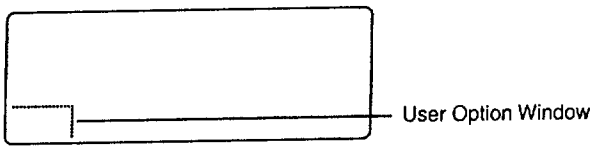
Your programmer's display screen is comprised of five components to assist you with its operation.

When any key is pressed, the display will "light-up." After 10 seconds the light will turn off. After 1 minute of inactivity the Programmer will automatically turn off. Press any key except the Power key to "light-up" the display screen.

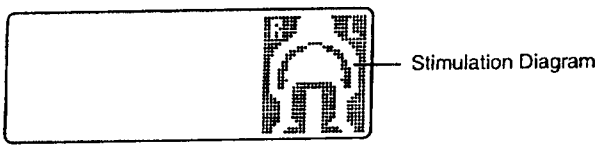
Program Number — The screen displays the present program number and number of stim sets in IPG.



User's Option Window — Shows current operational mode. **P** indicates program selection mode. **M** indicates menu selection mode. A blank user option window indicates normal stimulation operational mode.

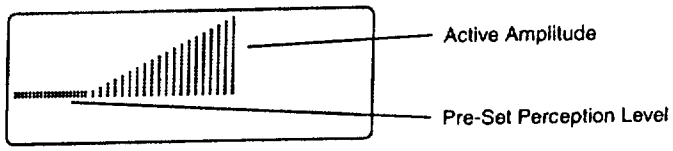


Stimulation Diagram — Graphically shows the area of stimulation coverage for a given program.

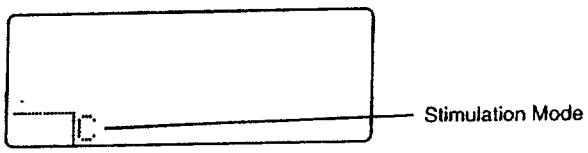


NOTE: If stimulation diagrams were not included as part of the therapy, then the following symbol will be displayed.

Active Amplitude — Graphically shows the current amplitude setting.



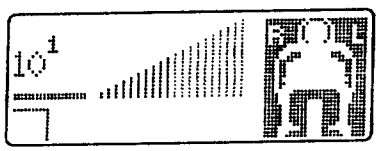
Stimulation Mode — Shows the stimulation mode (Continuous, Bolus, or Cycle). See stimulation mode section for specifics.



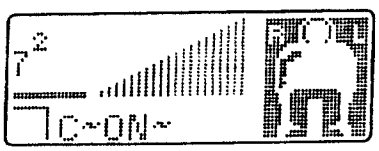
Stimulation Modes

The Genesis Neurostimulation System provides several delivery modes for patient therapy. These modes are Continuous, Cycle and Bolus mode. Each mode is described below.

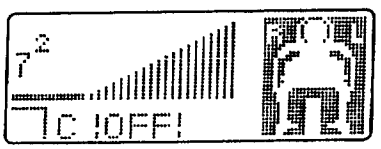
Continuous Mode — This mode provides continuous stimulation to the patient. When the system is turned on, therapy is delivered until the system is manually turned off. Continuous mode does not display a visual prompt.



Cycle Mode — Cycling allows the physician to set selected time intervals for on and off times. This allows cycling of the therapy for battery conservation and stimulation refinement. Two screens will be displayed in this mode, either "Cycle On" mode or "Cycle Off" mode. The visual prompt for the cycle mode is "C." Samples of both are displayed below. Cycle times over one minute will display countdown times in On and Off phases.

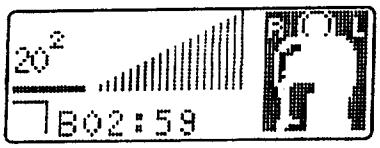


Cycle On

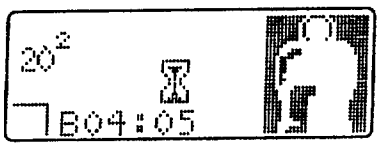


Cycle Off

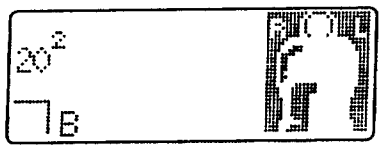
Bolus Mode — Bolus mode allows the IPG to have predetermined on and lock-out (off) periods. This enables activation for a physician prescribed duration. Upon completion, the system will enter a preset lock-out period during which no stimulation is available. Stimulation can be activated again when the lock-out period is complete. There are three potential screens when the IPG is on. The visual prompt for the Bolus mode is "B."



Bolus On



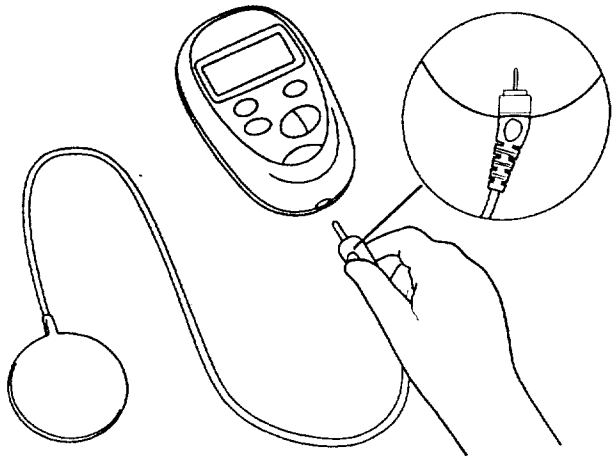
Bolus Lock Out



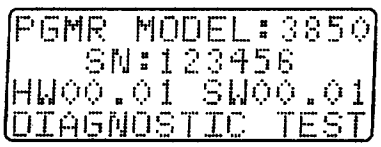
Bolus Ready

STARTING YOUR GENESIS SYSTEM

1. Plug the programming wand into the programmer. Grasp the wand plug and gently insert the pin into the opening in the bottom of the programmer. The plastic end should extend partly into the case, and you should feel a slight snap when the wand is properly connected.



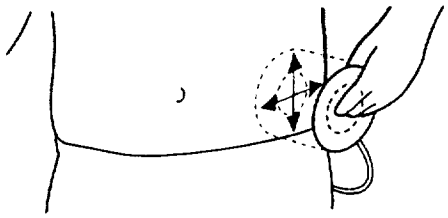
2. Turn on the programmer by pressing the red colored Programmer Power On/IPG Off Key ⏻.



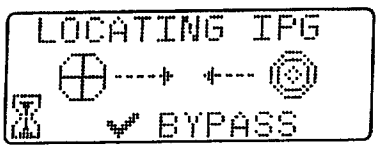
NOTE: The diagnostic screen shows for approximately two seconds.

POSITIONING THE WAND

1. Position the wand directly over the IPG to establish communication with the IPG.



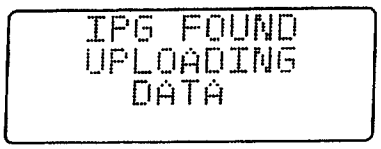
NOTE: An audible tone will sound signifying active communication. This will last for 18 seconds or when the IPG is located, whichever is first.



NOTE: Once communication is established, do not move the wand. Successful use of the Genesis Programmer is dependent upon wand position.

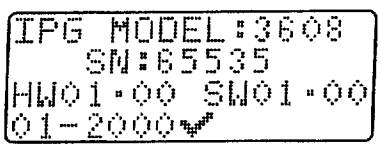
NOTE: IPG/Programmer communication can be interrupted by "electrical noise." For good communication, ensure you are away from electrical equipment (e.g., computer monitors).

2. Programmer/IPG communication is now being established.



NOTE: The program information presently stored and used in the IPG is being uploaded to the Programmer.

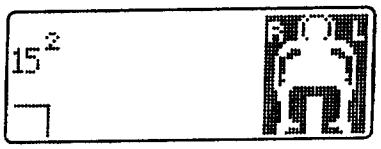
3. The IPG information screen is now displayed.



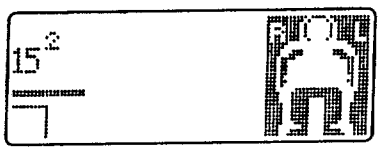
NOTE: Removal of the wand from the IPG site will discontinue IPG communications.

TO BEGIN STIMULATION

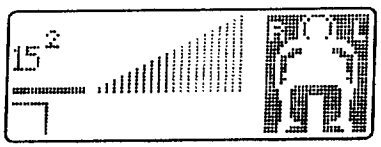
Immediately after the information screen is displayed, the operational screen (shown below) will appear. This screen indicates that the IPG is in the Off state, no stimulation is being provided and the device must be turned on for stimulation.



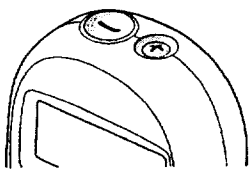
1. Push the Amplitude Up key ⊕ once. The amplitude will automatically advance to a preprogrammed perception level as indicated by the horizontal bar under the program number. This may take a few seconds to occur.



2. Press the Amplitude Up key ⊕ repeatedly or press and hold until stimulation is felt at a comfortable level. As the level of stimulation increases, the bars on the display rise. **You should feel increased stimulation.**



3. Reduce your level of stimulation by pressing the Amplitude Down key ⊖. You may adjust the stimulation level at any time by simply pushing the amplitude up or down keys. Their distinctive shape allows you to identify them without having to look at the programmer.



INTRODUCTION TO PROGRAM SELECTION* *(Optional Features)*

As part of your SCS therapy, your physician may have entered several stimulation programs into your programmer to utilize the Patient-Controlled Stimulation (PC-Stim®) feature. Each of these programs can include up to two stim sets that may change the quality of your sensation and/or the area of the body stimulated.

> ** This is an **optional feature** for specific pain conditions and **may not be included** as part of your therapy. Your physician will let you know if your therapy includes multiple stimulation programs.*

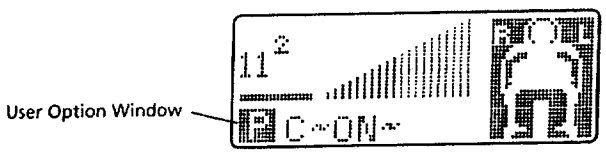
PROGRAM SELECTION

1. Press the Scroll keys ◀▶ until **P** is displayed in the User Option Window.

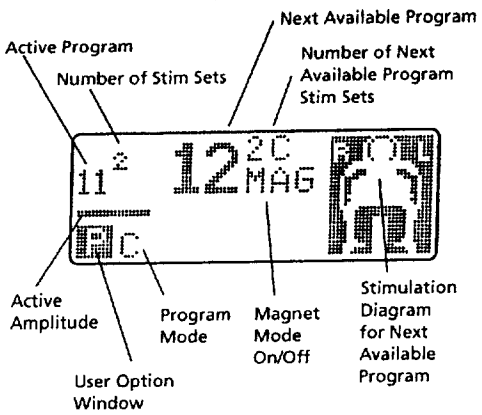
   NOTE: If multiple programs are not loaded in the programmer, the **P** *will not be displayed.*

   NOTE: The + and – keys are active during program review and if pressed will return the display to the Operational Display Screen and cause the amplitude to change as requested.

THE OPERATIONAL DISPLAY SCREEN



2. Press the Select key ✓ and the Program Selection Screen is displayed.



3. Press the Scroll keys to view other available programs and corresponding stimulation diagrams (if available).

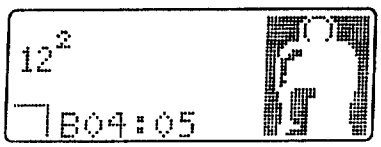
THE PROGRAM SELECTION SCREEN

NOTE: If stimulation diagrams were not included as part of your therapy as determined by your physician, then the graphic below will be displayed.

4. Press the Select key to select the desired program. The display will return to the Operational Display Screen.

NOTE: When you change programs the amplitude will automatically be turned off.

5. Press the Amplitude Up key to begin stimulation.

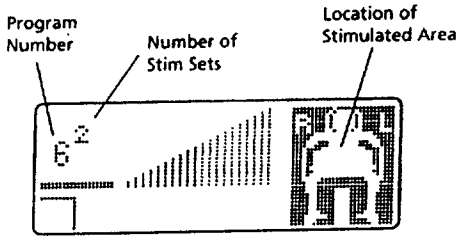


USING THE BALANCE CONTROL

The Balance Control allows you to adjust the amplitude of single and MultiStim programs to reach your optimal stimulation level. In either program type you may need more or less stimulation than your prescribed settings allow. The balance key enables you to manually bypass the pre-established settings. The balance key also allows you to adjust multiple stim sets within a MultiStim program, ensuring comfort for all areas covered.

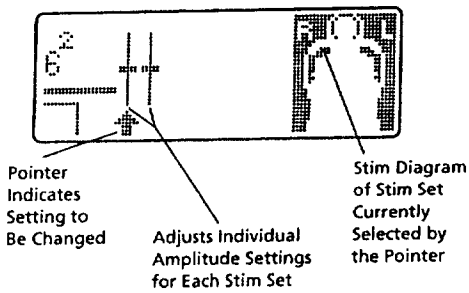
1. Press the Amplitude Up key ⊕ to begin stimulation.

A MULTISTIM PROGRAM



2. Push the Balance key ⊕⊕.

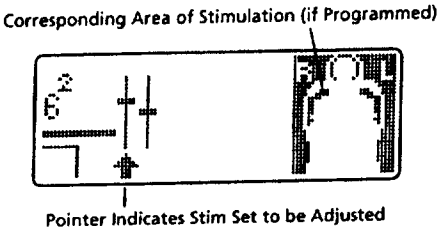
TO FINE-TUNE AMPLITUDE BALANCE WITHIN A PROGRAM:



NOTE: If the amplitude is at zero, the screen below will be displayed. Increase the amplitude to adjust.

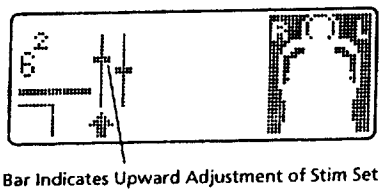
NOTE: A stimulation diagram will only appear when it has been entered by your clinician.

3. Press the Scroll keys to scroll through individual stim sets.



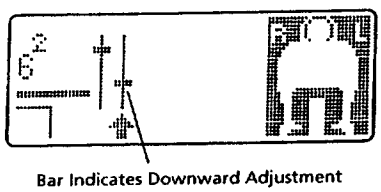
NOTE: Only one stim set adjustment bar will be displayed for a single type program.

4. Adjust the Amplitude by pressing the Amplitude Up key or Amplitude Down key .



NOTE: This will only change the amplitude of the indicated stim set.

5. Repeat steps 1-4 for other stim set, if desired.



6. Press the Select key to activate the changes. **You may readjust individual stim sets as often as you like.** When you restart your system or load a new program, all stim set values revert back to the pre-set values established by your doctor.

NOTE: You may cancel any changes by pressing the Previous Screen key prior to pressing select.

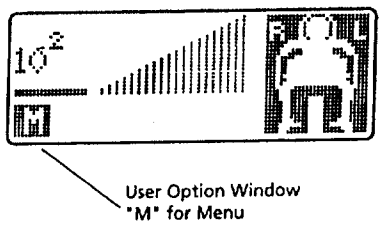
FINE-TUNING YOUR SYSTEM

The Menu Display Screen allows the fine-tuning of the visual display, sound volume and review of authorization and device status.

ENTERING THE MENU DISPLAY SCREEN

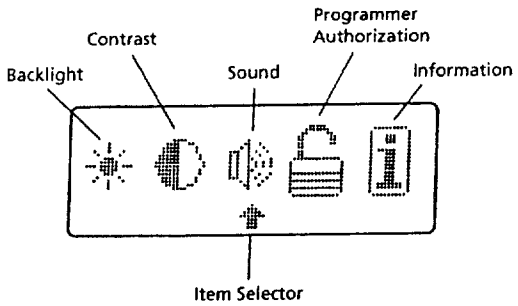
1. From the Operational Display Screen, press the Scroll keys ◀▶ until an **M** is displayed in the User Option Window.

THE OPERATIONAL DISPLAY SCREEN



2. Press the Select key ✓ and the Menu Screen will display.

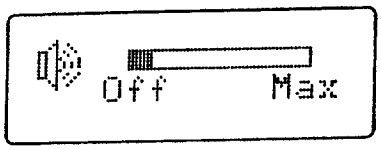
THE MENU SCREEN



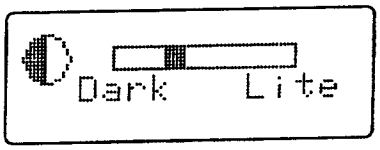
NOTE: The amplitude level will remain constant while reviewing or changing all menu preferences.

To Change or Adjust a Menu Preference:

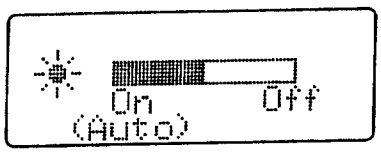
1. Press the Scroll keys to highlight the desired preference, then press the Select key.



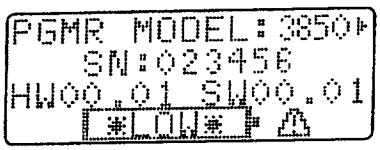
Sound — Press the Scroll keys to change the volume or turn sound off.



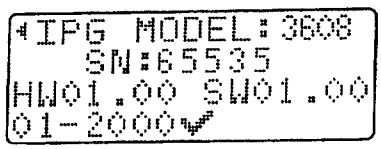
Contrast — Press the Scroll keys to change the display contrast.



BackLighting — Press the Scroll keys to change the backlighting of display.



Programmer Information — Displays information about the programmer.



IPG Information — Displays information about the IPG.

Programmer Authorization — Displays information about Genesis programmer and IPG authorization.

2. Press the Scroll keys to change preferences.
3. Upon completion of desired change, use the Select key to save the new setting.

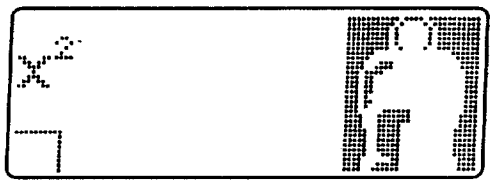
NOTE: You may cancel any changes by pressing the Previous Screen key prior to pressing select.

NOTE: Use of the Amplitude Up key and Amplitude Down key will return you to the Operational Display Screen in addition to making the amplitude change.

PARTIALLY AUTHORIZED PROGRAMMERS

Your Genesis Programmer is specifically authorized to work with your IPG. It is fully capable of accessing and downloading all programs and stimulation parameters. If your programmer is not available, your physician can use another programmer to adjust the stimulation parameters in your IPG. When this occurs the screen below will be displayed on your programmer.

This shows that the program stored in the IPG does not match any of the programs stored in the programmer and was adjusted by another programmer. If the program is effective, have your physician or representative store the program in your Genesis Programmer.

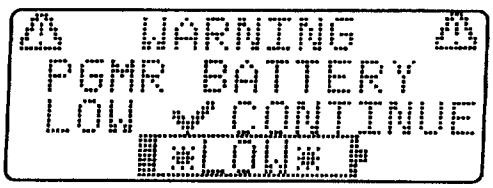


NOTE: If you change programs without saving the "X" program, the "X" program will be lost.

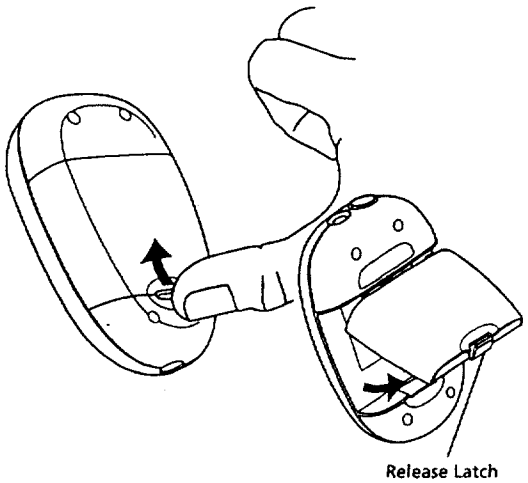
PROGRAMMER BATTERY INFORMATION

The programmer is powered by three AAA alkaline batteries contained in the battery pack.

When the battery power is low, an audio alarm will sound and this screen will be displayed. You should replace your AAA batteries.



BATTERY REMOVAL AND INSTALLATION

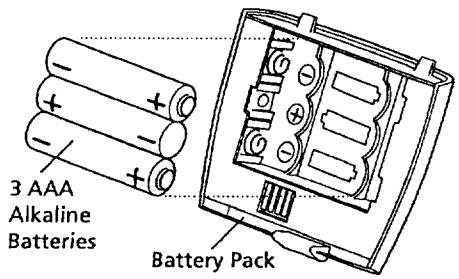


1. Ensure the programmer power is Off.
2. Push and hold the battery release latch on the bottom rear of the battery compartment.
3. Lift the battery pack from the programmer.

THE PROGRAMMER BATTERY PACK

The Genesis Programmer comes with three AAA batteries and a battery pack that fits into the programmer battery compartment.

1. Insert the batteries into the battery pack. Be sure to line up the + and – signs on the batteries with the signs in the battery compartment. The AAA batteries included with your Programmer are not rechargeable.



NOTE: If needed, additional AAA alkaline batteries can be obtained from retail stores.

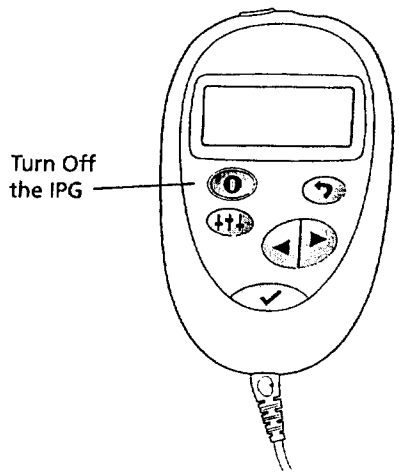
TO END STIMULATION

Your Genesis system can be turned off with the programmer or a magnet. To use the magnet refer to the next section. There are two methods to end stimulation with the Genesis programmer, both require you to establish communication with the IPG.

1. Ensure communication with the IPG. *(See Starting Your Genesis System on page 18.)*
2. Push the Amplitude Down key ⊖ to reduce the level of stimulation until it is not felt.

OR

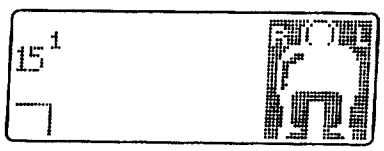
1. Turn off the IPG by pressing the Programmer Power On/IPG Off Key ⏻.



NOTE: *If you need to end stimulation immediately, press the Programmer Power On/IPG Off Key ⏻ to turn the IPG off.*

NOTE: *The patient programmer will turn off automatically after 60 seconds of inactivity. There is no manual way to turn off the programmer once it is powered on except by removing the battery pack which is not recommended during normal operation.*

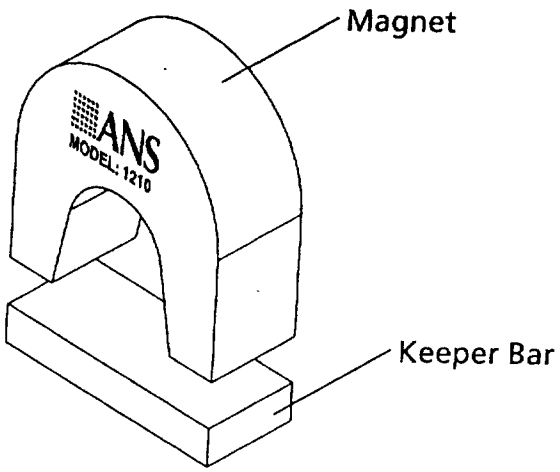
The programmer will display that stimulation is off.

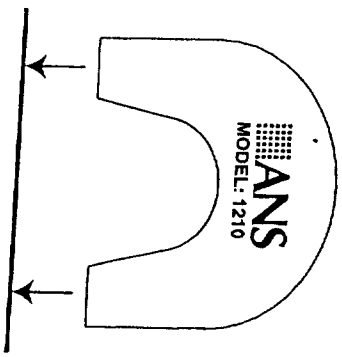


USING YOUR MAGNET

The Genesis system is provided with a magnet that is able to turn the IPG off at any time. The magnet can also be used to turn on the IPG when your physician activates the magnet mode. The IPG can be placed in two magnet modes, either magnet "Off" or magnet "On/Off." When selected, the magnet "On/Off" mode will be displayed as [MAG] in the Program Selection window. To use your magnet follow these steps:

1. Take the keeper bar off the magnet.





2. Place the magnet directly over the IPG.
3. Hold in place for 2 seconds.
4. Remove the magnet, replace the keeper bar and store the magnet.

CAUTION: The magnet provided with your Genesis system is a high powered magnet intended for use solely with the Genesis system. Keep your magnet away from watches, credit cards, computer disks and other magnetic sensitive items to avoid damage to them. Always place the "Keeper Bar" on the magnet when not in use.

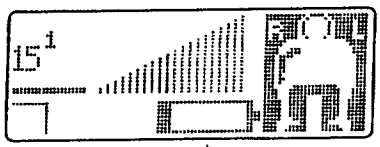
GENESIS SYSTEM END OF LIFE

The Genesis IPG will provide you with warning before the battery is totally depleted and the system needs replacing. Battery life depends on the power output you require and the amount of time you use the device.

1. The Genesis system will display the screen below on the programmer when the IPG battery is low.

When you encounter this warning screen:

2. Press the Select key ✔ to continue with normal stimulation and contact your physician to inform him your IPG battery is low.
3. Upon continuing stimulation, a low battery icon will appear on your user's option screen to remind you to call your physician.



Low Battery Icon

CARING FOR YOUR PROGRAMMER

PROGRAMMER SYSTEM CARE

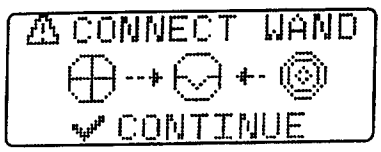
The programmer should be handled with care. It is a sensitive electronic device that can be damaged by rough handling, including dropping it on the floor.

- The programmer and wand are not waterproof; therefore limit activity that might cause them to get wet.
- Clean your programmer by wiping off the outer surface using a moist cloth and a small amount of mild soap. Do not submerge the programmer or wand in liquids or use a cloth that is saturated. Do not use alcohol, cleaning solutions or solvents to clean the programmer or wand.
- Do not allow the connector that plugs into the programmer to get wet. Do not pull on the wand cable to disconnect it from the programmer. Instead, grasp the connector where it plugs into the programmer and gently pull until it releases from the receptacle.
- Do not expose programmer to prolonged direct sunlight or extreme temperatures [below 14° F (–10° C) or above 131° F (55° C)].

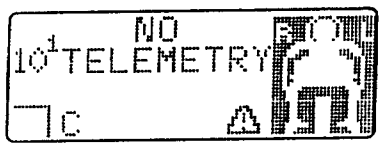
TROUBLESHOOTING

Diagnostic Messages

The programmer contains an automatic diagnostic program that continuously performs a system check during operation. If a malfunction or abnormal condition is detected relating to the programmer, IPG, or wand, a diagnostic screen is displayed and advises you of the situation and what to do next. The following are the common diagnostic screens:



Wand Connection Error — Check connection of the wand to programmer.



No Telemetry — IPG location was interrupted by pressing the Select key . No communication is established in this mode. Let the Programmer turn off and recommunicate with the IPG.

Programmer Batteries Low — Replace the batteries in the Programmer (see page 26).

IPG Battery Low — Press the Select key and call your physician to notify him of a low IPG battery (see page 31).

Diagnostic Error — Call ANS Customer Service for instructions.

System Error — Call ANS Customer Service for instructions.

Bad Program — Select another program or have your physician edit the present program.

IPG Communication Error — Reposition wand and press the Select key ✓.

NOTE: *IPG/Programmer communication can be interrupted by "electrical noise." For good communication, ensure you are away from electrical equipment (e.g., computer monitors).*

Wrong IPG Type — Call ANS Customer Service for instructions.

Changes In The Stimulation Sensation

During the recovery or healing period (which is usually 4-6 weeks), changes in the stimulation sensation can occur that may cause it to be perceived as more or less intense. Situations that may cause this include:

- Shifting your body position, such as lying down or leaning back in a chair, may cause the stimulation sensation to be more intense.
- Changing physical posture, such as leaning forward or arching your back, may cause the stimulation sensation to be less intense.
- Standing or walking may cause the stimulation sensation to be less intense.
- Straining to cough, or when having a bowel movement.
- Lifting an object heavier than a gallon of milk (8 pounds). Remember that lifting is to be avoided during the recovery period.

To decrease the possibility of experiencing uncomfortable stimulation, ANS recommends turning the amplitude down or the IPG off before assuming these positions.

After the recovery period, changes in stimulation should decrease with changes in posture or physical positions. However, changes can still occur when coughing, straining with a bowel movement or lifting an object. It is important to follow your physician's guidelines for physical activities and lifting.

If your stimulation pattern changes from your painful areas, or it becomes uncomfortable beyond your ability to control it by adjusting the amplitude, turn the IPG off and contact your physician.

What To Do If Something Seems Wrong

If you suspect that something may be wrong with your IPG, the following steps may help solve the problem:

1. Use your programmer to establish communication with your IPG.
2. Inspect the display screen for a diagnostic message.
3. Ensure the IPG is not in the cycle or bolus "Off" state (see page 16).
4. Check that the amplitude is adjusted to the correct and comfortable level.
5. If you still do not achieve the best results, call your physician's office. If the programmer does not operate, call ANS Customer Service at 1 (800) 727-7846 or (972) 309-8000.

TROUBLESHOOTING GUIDELINES

Problem/Symptom	Possible Cause	Possible Corrective Action
Uncomfortable Stimulation	Positional or inadvertent programming changes	Decrease amplitude. If unable to correct, turn IPG off and call physician's office.
No Stimulation	Amplitude set too low	Increase amplitude until comfortable stimulation is achieved.
	IPG in "off" phase	Check to see if the IPG is in Cycle or Bolus "off" phase. Wait until phase is completed. (See page 16.)
	Power is off	Check to see that IPG power is on.
	Depleted IPG battery	Call physician's office.
	Inadvertent programming change	Call physician's office.
	Program load error	Attempt to reload a new program. Call physician if ineffective.
	Implant Damage	Call ANS Customer Service at 1 (800) 727-7846 or (972) 309-8000.

TROUBLESHOOTING GUIDELINES *(continued)*

Problem/Symptom	Possible Cause	Possible Corrective Action
Intermittent Stimulation	Positional sensitivity	Refer to "Changes in Stimulation" and adjust amplitude accordingly. (See page 34.) Call physician's office if unable to adjust satisfactorily.
	Implantable system damaged or malfunctioning	Call ANS Customer Service at 1 (800) 727-7846 or (972) 309-8000.
Ineffective Stimulation	Positional changes	Refer to "Changes in Stimulation" and adjust amplitude accordingly. (See page 34.) Call physician's office if unable to adjust.
	Programmer damaged or malfunctioning	Call ANS Customer Service at 1 (800) 727-7846 or (972) 309-8000.

TROUBLESHOOTING GUIDELINES *(continued)*

Problem/Symptom	Possible Cause	Possible Corrective Action
Changes in Stimulation Coverage	Positional changes	Refer to "Changes in Stimulation" and adjust amplitude accordingly. (See page 34.) Call physician's office if unable to adjust satisfactorily.
No Control of IPG with Programmer	Wand positioned incorrectly	Reposition wand over the IPG.
	Wand not inserted properly	Reinsert wand.
	Noisy electrical environment	Move to another area and try again.
	Wand damaged	Call ANS Customer Service at 1 (800) 727-7846 or (972) 309-8000.
	Programmer damaged or malfunctioning	Call ANS Customer Service at 1 (800) 727-7846 or (972) 309-8000.
No Programmer Power	Depleted batteries	Replace Programmer batteries with new AAA batteries.
	Battery pack or AAA batteries not inserted properly	Reinsert battery pack or AAA batteries.
	Programmer damaged or malfunctioning	Call ANS Customer Service at 1 (800) 727-7846 or (972) 309-8000.
No Programmer Display	Power is off due to automatic time out	Push the Programmer Power On/IPG Off Key ⏻.
	Depleted batteries	Replace Programmer batteries with new AAA batteries.

LIMITED WARRANTY

GENERAL WARNING

A. Advanced Neuromodulation Systems, Inc. Genesis Neurostimulation Systems are comprised of implantable components, programmers and patient accessories. The patient accessories include wands, batteries and system magnet. The implantable components include leads/lead kits, IPG kits, extensions and accessories. Upon being implanted, these components must withstand exposure to an extremely hostile and unpredictable environment in the human body. The implanted components may fail during or following implantation into the body for any one or a number of reasons, including, but not limited to: medical complications, body rejection phenomena, lead breakage, or improper handling, implantation or use, or insulation breach.

B. Advanced Neuromodulation Systems, Inc. makes no representations or warranties that failure or cessation of function of any component, or the system, will not occur; that the body will not react adversely to implantation; or that medical complications will not develop.

LIMITED WARRANTY

A. LIMITATION OF WARRANTY

Advanced Neuromodulation Systems, Inc., 6501 Windcrest Dr., Ste. 100, Plano, TX 75024, warrants the Advanced Neuromodulation Systems, Inc.'s Genesis Neurostimulation System to be free from defects in material or workmanship within one (1) year from the date of implantation or ownership, subject to the terms and conditions contained in this warranty. Only patient-customers who receive an Advanced Neuromodulation Systems Genesis Neurostimulation System and return a properly completed warranty registration card to Advanced Neuromodulation Systems, Inc. within 60 days from the date of surgery may enforce this limited warranty.

B. THIS LIMITED WRITTEN WARRANTY CONTAINS THE FINAL, COMPLETE AND EXCLUSIVE STATEMENT OF WARRANTY TERMS FOR ADVANCED NEURO-MODULATION SYSTEMS, INC. GENESIS NEURO-STIMULATION SYSTEMS, AND IT APPLIES IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED. ADVANCED NEUROMODULATION SYSTEMS, INC. DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. NO PERSON IS AUTHORIZED TO MAKE ANY OTHER GUARANTEES, WARRANTIES OR REPRESENTATIONS ON BEHALF OF ADVANCED NEUROMODULATION SYSTEMS, INC. This limitation may not apply to you because some states and countries prohibit the limitation or exclusion of implied warranties. You may have other rights under state law not specifically addressed in this limited warranty.

THIS LIMITED WARRANTY FOR THE GENESIS NEUROSTIMULATION SYSTEM DOES NOT APPLY TO:

1. Any damage caused by misuse, neglect, accident, modification, improper application, or from other than normal and ordinary use.

2. Any damage caused by any repair or attempted repair by one other than an authorized Advanced Neuromodulation Systems-trained technician.

3. Any damage resulting from failure to clean or use in accordance with the Operating Instructions and/or Services Manual furnished by Advanced Neuromodulation Systems.

C. LIMITATION OF DAMAGES

ADVANCED NEUROMODULATION SYSTEMS, INC. DISCLAIMS LIABILITY FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGE ARISING OUT OF, OR IN CONNECTION WITH, THE USE OR PERFORMANCE OF THE SYSTEM, WHETHER SUCH CLAIM IS BASED ON CONTRACT, TORT, WARRANTY OR OTHERWISE. This limitation of liability applies to all warranty claims. No waiver or amendment of this limited warranty shall be valid unless in writing signed by Advanced Neuromodulation Systems, Inc. Some states, and countries, do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation may not apply to you.

IMPLANTABLE COMPONENTS

A. Subject to Sections I and II and paragraph III(B), if any of the implantable components should fail to function due to a defect in material or workmanship during the warranty period, Advanced Neuromodulation Systems, Inc. will, at its option:

1. Replace the implantable component with an equivalent, or functionally equivalent, implantable component at no charge to the patient-consumer; or
2. Issue a credit to the patient-consumer for a replacement Advanced Neuromodulation System implantable component, the credit being equal to the net invoice price for the replaced implantable component.

B. For repair, replacement or credit under this limited warranty:

1. The implantable component must be implanted prior to the expiration date indicated on the component's packaging, and
2. If the implantable component is explanted, the patient-consumer, his or her authorized representative, physician or hospital, must return the component to Advanced Neuromodulation Systems. The patient-consumer, or his or her authorized representative, must, at his or her own expense, mail or ship the product together with a Return Merchandise Authorization number obtained from Customer Service to Advanced Neuromodulation Systems, Inc. within 30 days after explantation. If the implantable component is not explanted, the component's serial number or lot number must be provided within 30 days after discovery of the defect.
3. Upon Advanced Neuromodulation Systems Inc.'s receipt of the product, the returned implantable component shall become the exclusive property of Advanced Neuromodulation Systems, Inc.

PROGRAMMERS AND PATIENT ACCESSORIES

A. Subject to Sections I, II and paragraph IV(B), if any System programmer or patient accessory fails to function due to a defect in material or workmanship during the warranty period, Advanced Neuromodulation Systems, Inc. will, at its option:

1. Repair any defective part of the programmer or accessory at no charge to the patient-consumer; or
2. Replace the programmer or accessory with an equivalent, or functionally equivalent, programmer or accessory at no charge to the patient-consumer; or
3. Issue a credit to the patient-consumer for a replacement Advanced Neuromodulation Systems programmer or accessory in an amount equal to the net invoice price for the defective programmer or accessory.

B. For repair, replacement or credit under this limited warranty:

1. The patient-consumer, or his or her authorized representative, must, at his or her own expense, mail or ship the product together with a Return Merchandise Authorization number obtained from Customer Service to Advanced Neuromodulation Systems, Inc. within 30 days after discovery of the defect.
2. Upon Advanced Neuromodulation Systems, Inc.'s receipt of the product, the returned component shall become the exclusive property of Advanced Neuromodulation Systems, Inc

CUSTOMER SERVICE INFORMATION

ORDERING INFORMATION / ASSISTANCE

For questions or requests for assistance contact:

U.S.A. and Others:
ANS Customer Service
6501 Windcrest Drive, Suite 100
Plano, TX 75024

Tel: (800) 727-7846
(972) 309-8000
Fax: (972) 309-8150

Europe:
ANS European Representative
12 Squirrel Rise, Marlow Bottom
Buckinghamshire
SL7 3PN United Kingdom

NOTES

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Advanced Neuromodulation Systems, Inc.
6501 Windcrest Drive, Suite 100 / Plano, Texas 75024
(800) 727-7846 / (972) 309-8000 / www.ans-medical.com

37-0359-01 REV C
NOV 01

Genesis™

Neurostimulation System

Clinician's Manual

ABOUT THIS MANUAL

This manual is intended to explain the operation of the ANS Genesis™ System. It includes information about system components, the implant procedure, and device programming. The system includes the following components:

3608	8-Channel Implantable Pulse Generator
3143	Quattrode® Percutaneous Lead Kit, 30cm, 3/4 Spacing
3146	Quattrode® Percutaneous Lead Kit, 60cm, 3/4 Spacing
3153	Quattrode® Percutaneous Lead Kit, 30cm, 3/6 Spacing
3156	Quattrode® Percutaneous Lead Kit, 60cm, 3/6 Spacing
3183	Octrode® Percutaneous Lead Kit, 30cm
3186	Octrode® Percutaneous Lead Kit, 60cm
3222	Lamitrode® 22 Surgical Lead Kit, 60cm
3240	Lamitrode® 4 Surgical Lead Kit, 60cm
3244	Lamitrode® 44 Surgical Lead Kit, 60cm
3280	Lamitrode® 8 Surgical Lead Kit, 60cm
3382	Extension, 20cm
3383	Extension, 30cm
3386	Extension, 60cm
3341	Dual Extension, 10cm
3342	Dual Extension, 20cm
3343	Dual Extension, 30cm
3346	Dual Extension, 60cm
3810	PainDoc® Computerized Support System
3850	Genesis Programmer
1210	Patient Magnet
1232	Programmer Wand
1253	Battery Pack for AAA Batteries
1272	System Storage Case

CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician.

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CONTENTS *(Continued)* **PAGE**

THE GENESIS IPG SYSTEM

The Genesis™ System is a multi-programmable implantable neurostimulation system designed to deliver low-intensity, electrical impulses to nerve structures. The system consists of an implantable pulse generator (IPG), an implanted lead(s) and a patient programmer.

The electrical impulses travel to the leads, which are connected to the IPG, and are delivered to selected nerve fibers in order to provide therapeutic stimulation. The patient programmer enables the patient to adjust current stimulation parameters and select new programs for customized therapy.

SYMBOLS AND DEFINITIONS

The following symbols are used in this manual or on the product package:

⚠	Notice for the reader to pay special attention to the details which follow
SN	Denotes serial number
⧗	Denotes expiration date
⊗	Denotes for single use only
LOT	Denotes batch code
	Denotes date of manufacture
LATEX FREE	Denotes latex free

CONTENTS OF PACKAGE

ANS neurostimulation devices, leads, and accessories have been sterilized using ethylene (EtO) oxide gas before shipment and are supplied in sterile packaging to permit direct introduction into the operative field. The Programmer is supplied unsterile. An expiration date (or use-before date) is marked on the label of each package.

The package contents of the Genesis IPG Kits are as follows:

MODEL 3608

1 each	IPG
2 each	Connector Strain Reliefs
1 each	Torque Wrench
1 each	Tunneling Tool
1 each	Clinician Manual
1 each	Registration Card

The package contents of the Patient Programmer Kit are as follows:

MODEL 3850

1 each	Genesis Programmer	1 each	Carrying Case
1 each	Battery Pack	1 each	Patient Manual
3 each	AAA Batteries	1 each	Patient Video
1 each	Programming Wand	1 each	Patient Information Packet
1 each	Registration Card	1 each	Magnet

INDICATIONS FOR USE

The Genesis (IPG) Neurostimulation System is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs including unilateral or bilateral pain associated with any of the following: failed back surgery syndrome, and intractable low back and leg pain.

CONTRAINDICATIONS

The system is contraindicated for patients with demand type cardiac pacemakers.

Patients that are unable to operate the system or fail to receive effective pain relief during trial stimulation cannot be implanted with a SCS.

⚠ WARNINGS

Spinal Cord Stimulation (SCS) should not be used on patients that are poor surgical risks, those with multiple illnesses or active general infections.

Diathermy Therapy – Do not use short-wave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy is further prohibited because it may also damage the neurostimulation system components resulting in loss of therapy, requiring additional surgery for system implantation and replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned "On" or "Off." All patients are advised to inform their health care professional that they should not be exposed to diathermy treatment.

Cardioverter Defibrillators – Neurostimulation systems may adversely affect the programming of implanted cardioverter defibrillators.

Magnetic Resonance Imaging (MRI) – Patients with implanted neurostimulation systems should not be subjected to MRI. The electromagnetic field generated by an MRI may dislodge implanted components, damage the device electronics and induce voltage through the lead that could jolt or shock the patient.

Explosive or Flammable Gases – Do not use the patient programmer in an environment where explosive or flammable gas fumes or vapors are present. The operation of the patient programmer could cause them to ignite, causing severe burns, injury or death.

Theft Detectors and Metal Screening Devices – Certain types of antitheft devices such as those used at entrances/exits of department stores, libraries, and other public establishments, and/or airport security screening devices may affect stimulation. It is possible that patients who are implanted with non-adjacent multiple leads and/or patients that are sensitive to low stimulation thresholds may experience a momentary increase in their perceived stimulation, which has been described by some patients as uncomfortable or jolting. It is recommended that patients use caution when approaching such a device and request assistance to bypass the device. If they must proceed through the device the patient should turn off the stimulator and proceed with caution, ensuring to move through the detector quickly.

Lead Movement – Patients should be instructed to avoid bending, twisting, stretching, or lifting objects over five pounds, for six to eight weeks post-implantation. Extension of the upper torso or neck may cause lead movement and alter the stimulation field (especially with leads in the cervical area), resulting in overstimulation or ineffective stimulation.

⚠ WARNINGS *(Continued)*

Operation of Machinery and Equipment – Patients should not operate potentially dangerous machinery, power tools, vehicles, climb ladders, etc., when the IPG is operating. Postural changes or abrupt movement could alter the perception of stimulation intensity and cause patients to fall or lose control of equipment or vehicles, injure others, or bring injury upon themselves.

Postural Changes – Changes in posture or abrupt movements may result in a decrease or increase in the perceived level of stimulation. Perception of higher levels of stimulation has been described by some patients as uncomfortable, painful, or jolting. Patients should be advised to turn down the amplitude or turn off the IPG before making extreme posture changes or abrupt movements such as stretching, lifting of arms over head, or exercising. If unpleasant sensations occur, the IPG should be turned off immediately.

Pediatric Use – Safety and effectiveness of spinal cord stimulation has not been established for pediatric use.

Pregnancy – Safety for use during pregnancy has not been established.

Device Components – The use of non-ANS components with this system may result in damage to the system and increased risk to the patient.

Case Damage – If the IPG case is pierced or ruptured, severe burns could result from exposure to the battery chemicals.

PRECAUTIONS

General Precautions

Physician Training – Implanting physicians should be experienced in the diagnosis and treatment of chronic pain syndromes and have undergone surgical and device implantation training.

Patient Selection – It is extremely important to appropriately select patients for spinal cord stimulation. Thorough psychiatric screening should be performed. Patients should not be dependent on drugs and should be able to operate the stimulator.

Infection – It is important to follow proper infection control procedures. Infections related to system implantation might require that the device be explanted.

Implantation of Two Systems – If two systems are implanted, ensure that at least 8 in. (20 cm) separates the implanted IPGs to minimize the possibility of interference during programming.

Implantation of Multiple Leads – If multiple leads are implanted, leads and extensions should be routed in close proximity. Nonadjacent leads have the possibility of creating a conduit for stray electromagnetic energy that could cause unwanted stimulation in the patient.

High Stimulation Outputs – Stimulation at high outputs may cause unpleasant sensations or motor disturbances, or render the patient incapable of controlling the patient programmer. If unpleasant sensations occur, the device should be turned off immediately.

Stimulation Parameters – Patients should be cautioned that stimulation parameters must be determined under the supervision of a physician and that they should not adjust stimulation parameters within prescribed programs except under direct orders from their physician.

Cellular Phones – The effect of cellular phones on spinal cord stimulators is unknown and patients should avoid placing cellular phones directly over the device.

FCC Statement – FCC ID: PX2001 – This device (Patient Programmer) complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Sterilization and Storage

Single-Use Device – The implanted components of the ANS Genesis IPG System are intended for a single-use only. Do not resterilize or reimplant an explanted system for any reason because of risk of infection and device malfunction.

Storage Temperature – Store system components between -10°C (14°F) and 55°C (131°F) because temperatures outside this range can damage components.

Storage Humidity – Store components between 10% and 90% humidity.

Handling, Implementation, and Explantation

Expiration Date – Do not implant a device if the use-before date has expired.

Care and Handling of Components – Use extreme care when handling system components prior to implantation. Excessive heat, excessive traction, excessive bending, excessive twisting or the use of sharp instruments may damage and cause failure of the component.

Package and Component Damage – Do not implant a device if the sterile package or components show signs of damage, the sterile seal is ruptured, or if contamination is suspected for any reason. Return to ANS for evaluation.

Exposure to Body Fluids or Saline – Prior to connection, exposure of the metal contacts, on the connection end of the lead or extension, to body fluids or saline can lead to corrosion. If this occurs, clean with sterile, deionized or distilled water and dry completely prior to lead connection and subsequent implantation.

System Testing – The operation of the system should always be tested after implantation and before the patient leaves the surgery suite to assure correct operation.

Component Disposal – Return all explanted components to ANS for safe disposal.

Hospital and Medical Environments

High Output Ultrasonics and Lithotripsy – The use of high output devices such as an electrohydraulic lithotriptor may cause damage to the electronic circuitry of an implanted IPG. If lithotripsy must be used, do not focus the energy near the IPG.

Ultrasonic Scanning Equipment – The use of ultrasonic scanning equipment may cause mechanical damage to an implanted neurostimulation system if used directly over the implanted device.

External Defibrillators – The safety of discharge of an external defibrillator on patients with implanted neurostimulation systems has not been established.

Therapeutic Radiation – Therapeutic radiation may damage the electronic circuitry of an implanted neurostimulation system, although no testing has been done and no definite information on radiation effects is available. Sources of therapeutic radiation include therapeutic x-rays, cobalt machines, and linear accelerators. If radiation therapy is required the area over the implanted IPG should be shielded with lead.

Electrosurgery Devices – Electrosurgery devices should not be used in close proximity to an implanted neurostimulation IPG or lead(s). Contact between an active electrode and an implanted IPG, lead or extension can cause direct stimulation of the spinal cord and cause severe injury to the patient. If use of electrocautery is necessary turn the IPG off.

Home and Occupational Environments

Electromagnetic Interference (EMI) – Certain commercial electrical equipment (arc welders, induction furnaces, resistance welders), communication equipment (microwave transmitters, linear power amplifiers, high power amateur transmitters), and high voltage power lines may generate sufficient EMI to interfere with the neurostimulation system operation if approached too closely.

PROGRAMMING

The ANS Genesis System can be programmed manually with the Genesis Programmer. Manual programming with the Genesis Programmer is discussed on page 40.

ADVERSE EFFECTS

The implantation of a neurostimulation system involves risk. In addition to those risks commonly associated with surgery, the following risks are also associated with implantation, and/or use of a neurostimulation system:

- Undesirable changes in stimulation may occur over time. These changes in stimulation are possibly related to cellular changes in tissue around the electrodes, changes in the electrode position, loose electrical connections and/or lead failure.
- Placement of a lead in the epidural space is a surgical procedure that may expose the patient to risks of epidural hemorrhage, hematoma, infection, spinal cord compression, and/or paralysis.
- Battery failure and/or battery leakage may occur.
- Radicular chest wall stimulation.
- CSF leakage.
- Persistent pain at the electrode or IPG site.
- Seroma at the implant site.
- Lead migration, which can result in changes in stimulation and subsequent reduction in pain relief.
- Allergic or rejection response to implant materials.
- Implant migration and/or local skin erosion.
- Paralysis, weakness, clumsiness, numbness or pain below the level of implantation.

GENESIS (IPG) NEUROSTIMULATION SYSTEM CLINICAL SUMMARY

The safety and effectiveness of the Genesis (IPG) Neurostimulation System was determined based on available published clinical studies for similar totally implanted spinal cord stimulation systems. The ANS IPG device is similar to the SCS systems reported in published literature in intended use, target patient population, technology, device design, and output characteristics. Therefore, the clinical data from the published literature described below represents evidence supporting the safety and effectiveness of the Genesis (IPG) Neurostimulation System for use as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back and leg pain.

EFFICACY EVALUATION

Three (3) clinical literature studies were used to assess the safety and effectiveness of the Genesis (IPG) Neurostimulation System (Ohnmeiss et al. 1996, Villavicencio et al. 2000, Hassenbusch SJ et al. 1995). The studies included a total of 116 patients that were implanted with an SCS system. A total of approximately 3166 device months of experience was considered in the retrospective clinical evaluation. All three studies examined the effectiveness of SCS on patients with chronic pain of the trunk and/or limbs including unilateral or bilateral pain associated with the following: failed back surgery syndrome or intractable low back and leg pain. In all studies, an identified totally implantable spinal cord stimulator was used in association with a quadripolar percutaneous epidural lead or a quadripolar lead. These studies provide the same diagnostic or therapeutic intervention for the same disease/conditions and patient population as the Genesis (IPG) Neuromodulation System.

The prospective study by Ohnmeiss et al. 1996 examined the long-term effectiveness of SCS in patients with intractable leg pain. 40 patients were implanted with SCS systems and evaluated at 6 weeks, 12 months, and 24 months follow-up. Outcome measures included the VAS, pain drawings, medication use, SIP, isometric lower extremity testing, and patient questionnaires. An intent to treat analysis was performed. After patients had SCS for 24 months, leg pain, pain when walking, standing pain, pain's effect on overall lifestyle, and the total analog scale scores were significantly improved from baseline. In this study, SCS was effective in improving intractable leg pain.

In addition, 3 patients from this study had their stimulators repositioned due to pain at the original location. Three patients had reoperations to adjust lead position; 1 patient required 2 reoperations, 1to have the device removed due to infection and later to have a new device implanted. A diabetic patient had skin problems which required device removal; a new device was later implanted. Two patients had the device removed due to unsatisfactory pain relief.

The prospective study by Villavicencio et al. 2000 included 41 patients with pain of various etiologies. The majority of the patients, 24 (59%), had Failed Back Surgery Syndrome (FBSS), 7 (17%) had Complex Regional Pain Syndrome) CRPS I and II, 4 (10%) had neuropathic pain syndrome, and 6 (15%) were diagnosed as stroke or other. Patients underwent an initial trial period for SCS with temporary leads. If the trial resulted in greater than 50% reduction in the patient's pain, as measured by the VAS, the patient was implanted with a SCS system. In the study, 27/41 (66%) patients had permanent implants. All patients were examined after 6 weeks. Pain measurements were assessed at 3-6 month intervals for the first year and annually thereafter. The median long-term follow-up was 34 months. A total of 24/27 (89%) patients reported greater than 50% reduction in pain. Since the majority of the patients were treated for FBSS, this article supports the use of SCS for the treatment of FBSS.

In this study, 1 patient required a revision because of electrode fracture. One patient required removal of the system due to local infection. One patient required replacement of the IPG due to mechanical failure. Overall, 16 of 27 (59%) patients required a total of 36 repositioning procedures.

A retrospective analysis by Hassenbusch SJ et al. 1995 that included patients with chronic lower body pain, predominately neuropathic pain and pain either midline lower back and/or unilateral or bilateral leg pain treated over a 5 year period. The study was a comparison of SCS to spinal infusion of opioids. For patients with radicular pain involving one leg with or without unilateral buttock pain, a trial of SCS was recommended first. For patients with midline back pain and /or bilateral leg pain, a trial of long-term spinal infusion was recommended first. If the patients failed screening with either of these modalities, the other was then tested. If the treatment reduced the pain by 50%, the systems were internalized. A retrospective analysis of patients with unilateral leg and/or buttock pain treated initially with SCS and bilateral leg or mainly low back pain treated initially with spinal infusions of opioids was then done.

In this study, 42 patients were screened; 26 (62%) patients received spinal stimulation; 16 (38%) received opioids via a spinal infusion pump. A total of 5 patients did not receive adequate pain relief with SCS; 3 (7%) of these patients underwent trial spinal infusions and had effective pain relief. There were of 4 (10%) patients that underwent a trial of spinal infusion of opioid but did not receive adequate pain relief; these patients were not tested with SCS. Pain severity was rated using a verbal digital pain scale: "On a scale of 0 to 10 where 0 is no pain and 10 is the worst pain you could ever imagine, what is your pain now?" (Hassenbusch SJ et al. 1995) 16/26 patients (62%) had greater than 50% pain relief with SCS. A total of 2/16 (13%) patients had greater than 50% pain relief with opioids. Mean follow-up was 2.1 + 0.3 years. This analysis supports the use of SCS for intractable low back and leg pain.

In this study, 7 (17%) patients suffered complications after implantation of the device; 5 (12%) patients required repositioning of catheter type electrodes and 2 patients required revision of the stimulator generator.

SAFETY EVALUATION

Sixteen (16) studies were identified based on the detailed inclusion/exclusion criteria to demonstrate the safety of the Genesis (IPG) Neurostimulation System (all references in the Bibliography were used). The studies included a total of 1253 patients.

SUMMARY OF RISKS IDENTIFIED IN THE RETROSPECTIVE CLINICAL STUDIES

Risks	# of Patients	# of Events	% of Patients
Lead Migration	1059	144	13.6
Infection	1253	37	3.0
Epidural Hemorrhage	1253	0	0
Seroma	1253	0	0
Hematoma	1253	5	0.4
Paralysis	1253	1	0.1
CSF Leak	1253	6	0.5
Over/Under Stim	1059	27	2.6
Intermittent Stim	1059	0	0
Pain over Implant	1059	12	1.1
Allergic Reaction	1059	2	0.2
Skin Erosion	1059	1	0.1
Lead Breakage	1059	182	17.2
Hardware Malfunction	1059	32	3.0
Loose Connection	1059	10	1.0
Battery Failure	911	17	1.9
Other	1059	24	2.3

The above table depicts the number of patients, the number of events observed, and the percentage of occurrences of each event compared to the total number of patients. It should be noted that several studies include both IPG and RF Systems. The clinical experience reported in the literature on RF systems is relevant to determining the safety of totally implantable IPG systems.

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INDIVIDUALIZATION OF TREATMENT

Best results are obtained when the patient is fully informed about the therapy risks and benefits, implantation procedure, follow-up requirements, and self-care responsibilities. Spinal cord stimulation is appropriate for patients who meet the following criteria:

- Patients with chronic pain of the trunk or limbs, whose pain is physiological in origin and of the type treatable with spinal cord stimulation.
- Patients who are able to operate the device.
- Patients who are suitable candidates for surgery and free of active general infections.

Before a spinal cord stimulation system is implanted, the following conditions should be met:

- Patients have undergone a successful trial screening period.
- Patients have demonstrated a willingness to participate in the treatment protocol.

USE IN SPECIFIC POPULATIONS

The safety and efficacy of this device has not been established for uses not covered in the "Indications for Use" section of this manual or in patients who are:

- Pregnant or nursing
- Pediatric

PATIENT COUNSELING INFORMATION

The patient should be given simple and practical instructions regarding the operation and care of the SCS system. Guidelines should also be given about how posture and activity can affect stimulation as well as under what circumstances the physician should be contacted regarding device problems. Other patient instructions should include:

- Never operate the stimulator while driving a vehicle, operating power tools, or engaging in any other potentially hazardous activity. Postural changes or abrupt movement could alter the perception of stimulation intensity and cause patients to lose their balance or lose control of the equipment or vehicle.
- Certain types of antitheft devices such as those used at entrances/exits of department stores, libraries, and other public establishments and/or airport security screening devices may affect stimulation. Caution should be exercised when approaching such a device and assistance should be requested to bypass the device by presenting their Patient ID Card. If they must proceed through the device the patient should turn off the stimulator and proceed with caution, ensuring to move through the detector quickly.

- Avoid bending, twisting, stretching, or lifting objects over five pounds for six to eight weeks post-implantation. Extension of the upper torso or neck may cause lead movement and alter the stimulation pattern (especially with leads in the cervical area) resulting in ineffective stimulation.
- Changes in posture or abrupt movements may result in a decrease or increase in the perceived level of stimulation. Patients should be advised to turn down the amplitude or turn off the IPG before making extreme posture changes or abrupt movements such as stretching, lifting of arms over head, or exercising.
- Inspect the implant site frequently and contact the physician if redness, swelling or painful sensation occurs.
- If unpleasant stimulation sensations occur, the system should be immediately turned off.
- Amplitude and program selection are the only parameters that should be changed as a matter of everyday usage. Other parameter changes should be made only with permission of the physician.
- As amplitude, frequency, or pulse width is increased IPG battery life will be reduced.

SYSTEM DESCRIPTION

The Genesis IPG System consists of three primary components: the IPG, lead(s), and programmer.

The Genesis Neurostimulation System is intended to be used with ANS leads (3143, 3146, 3153, 3156, 3183, 3186, 3222, 3240, 3244, 3280) and extensions (3341, 3342, 3343, 3346, 3382, 3383, 3386).

IMPLANTABLE PULSE GENERATOR (IPG)

The Genesis IPG is an 8-channel multi-programmable system designed to be connected to one lead of 4 or 8 electrodes or one extension capable of dual leads (see Appendix C). It is powered by a hermetically sealed battery within a titanium case and uses microelectronic circuitry to generate constant current electrical stimulation. Stimulation programs can be delivered as either single stimulation or MultiStim® programs depending on the patient's needs.

The IPG is insulated on all sides except the side with markings. This allows the IPG to be used as an anode to facilitate unipolar stimulation. Ensure that the marked side is implanted up, away from any muscle.

In addition to the IPG, Genesis kits contain the following:

- **Connector Strain Relief(s)** (Model #1109) – Placed over the lead and inserted into the IPG connector assembly to function as a strain relief for the lead at the juncture where it exits the IPG connection
- **Torque Wrench** (Model #1101) – Used to tighten the set-screw on the connector assemblies of the IPG and extension
- **Tunneling Tool** (Model #1112) – Used to create a subcutaneous tunnel for routing the lead to the IPG site

LEADS

The leads are available in two configurations: percutaneous or surgical. Each lead consists of a variety of platinum iridium electrodes on the distal end connected by individually insulated wires to platinum iridium contact bands on the proximal end. The insulated wires are covered by a biocompatible polyurethane.

Percutaneous leads are designed for introduction into the epidural space using a special needle. The lead assembly consists of 4 or 8 cylindrical electrodes spaced at precise intervals. Percutaneous leads are supplied with a stylet to aid in positioning. Surgical leads are designed to be placed via a small incision or mini-laminotomy procedure. These leads consist of 4 or 8 plate-type electrodes, embedded in a silicone paddle. Lead specifications are listed in Appendix B on pages 57 and 58.

In addition to the lead, ANS percutaneous lead kits contain the following:

- **Guide Wire** (Model #1102) – Used to establish an appropriate pathway for the lead in the epidural space. The guide wire is 50 cm (20") in length
- **Trial Cable** (Model #3008) – Used to connect the lead to a test stimulator for intra-operative testing or for an extended trial procedure
- **Lead Anchor(s)** (Model #1105, #1106)– Made of silicone and used to secure the lead(s) to connective tissue for stability
- **Tunneling Tool** (Model #1112) – Used to create a subcutaneous tunnel to route the lead(s) to the IPG site
- **Epidural Needle** (Model #1114, #1115, #1116) – Special 14-gauge needle designed for insertion of the percutaneous leads into the epidural space
- **Introde-AK™ Lead Introducer** (Model #1103) – Radiopaque sheath designed to facilitate the insertion of the percutaneous lead to the epidural space and placement at the appropriate site
- **Lead Stylet(s)** (Model #1121, #1122, #1123, #1124) – Inserted in the lead body to assist in steering and positioning
- **Torque Wrench** (Model #1101) – Used to tighten the set-screw on the connector assemblies of the IPG and extension

In addition to a lead, the ANS surgical lead kits contain the following:

- **Lead Anchor(s)** (Model #1105, #1106) – Made of silicone and used to secure the lead(s) for stability
- **Trial Cable** (Model #3008) – Used to connect the lead to test stimulator for intra-operative testing or an extended trial procedure
- **Tunneling Tool** (Model #1112) – Used to create a subcutaneous tunnel for routing the lead(s) to the IPG site
- **Torque Wrench** (Model #1101) – Used to tighten the set-screw on the connector assemblies of the IPG and extension

PROGRAMMER

The Genesis Programmer controls the creation and adjustment of all programming parameters. Powered by three AAA batteries, the programmer communicates through the use of radio-frequency signals from the programmer wand to the implanted IPG. The programmer allows clinicians programming capability.

It also provides the IPG patient with Patient-Controlled Stimulation (PC-Stim®), empowering them to choose between several prescribed programs within the programmer memory.

X-Ray Identification

X-Ray identification allows the identification of the manufacturer and IPG model number. With standard x-ray procedures, the code inside the connector block is visible. For the ANS Genesis Model 3608, the code is ANS AXX, where "XX" designates the year of manufacture.

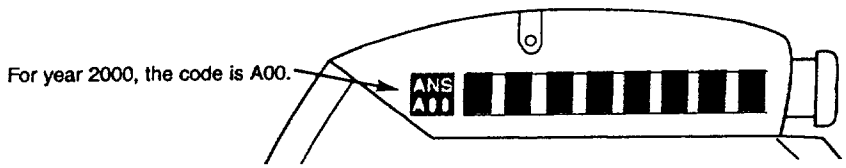

FIGURE 1

STERILIZATION INFORMATION

ANS pulse generator, leads, and accessories have been sterilized using ethylene oxide (EtO) gas before shipment and are supplied in sterile packaging to permit direct introduction into the operative field. The patient programmer is supplied unsterile. An expiration date (or use-before date) is marked on the label of each package.

CAUTION: ANS implantable components are intended for single use only. Do not resterilize.

SUGGESTED IMPLANT GUIDELINES

The physician should carefully review the following suggested guidelines for implantation of a Genesis IPG System. If a multiple-lead system is being implanted, repeat the appropriate steps for each lead.

Percutaneous Lead Placement

Percutaneous leads are designed for introduction into the dorsal epidural space using a special needle, guide wire and the optional Introde-AK (Introde) lead introducer. Each percutaneous lead is packaged with the accessories required to place the lead percutaneously (see Appendix A for specifications).

Implantation of a percutaneous lead should always be done with the aid of fluoroscopy. The physician should externally measure and determine the length of lead required to extend from the appropriate spinal level to the predetermined location of the implanted IPG. The appropriate vertebral level for needle entry should be identified and marked (Figure 2) to allow approximately 20 cm of the lead to lie in the epidural space. This will facilitate stabilization of the lead and electrodes following implantation. Typical entry levels for lead target sites include: